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10/516,307	12/10/2004	Hiroto Kikuchi	259431US0PCT	3909
22850	7590	12/30/2009	EXAMINER	
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P. 1940 DUKE STREET ALEXANDRIA, VA 22314				KOSAR, AARON J
ART UNIT		PAPER NUMBER		
		1651		
NOTIFICATION DATE			DELIVERY MODE	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/516,307	KIKUCHI ET AL.	
	Examiner	Art Unit	
	AARON J. KOSAR	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12 August 2009.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) _____ is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) _____ is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Response to Amendment

Applicant's amendment and argument filed August 12, 2009 in response to the non-final rejection, are acknowledged and have been fully considered. Any rejection and/or objection of record not specifically addressed is herein withdrawn.

Applicant has amended the claims by introducing new claims 60-65. Claims 43-65 are pending and have been examined on the merits.

Claim Objections

Claims 43, 54, and 56 are objected to because of the following informalities:

In claim 43, line 14, the term “difructose dianhydride III (DFA III)” is objected to because the abbreviation is previously associated with the expanded term in lines 2-3 and thus line 14 should recite the term -- DFA III -- . Claim 54 is objected to for the same reasons as claim 43 and thus included in this ground of objection. Appropriate correction is recommended.

In claim 56, the claim is objected to as being dependent upon a rejected base claim. Appropriate correction is recommended.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 43-53 are/remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 43 the phrase “thereby difructose dianhydride III” is unclear because the phrase omits a term after the term “thereby” and thus it is unclear if Applicant intends for the phrase to recite a concluding statement or if an active step or other interpretation is intended by the phrase. Clarification is required.

Claims 44-53 depend directly or indirectly from the rejected claims and are, therefore, also rejected under 35 USC § 112, second paragraph, for the reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 43, 45, 47-55, and 57-65 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka (AP, N' of record) or Uchiyama (A, of record) or Tomita (N), and in view of Saito (V":PTO-892: Katsuichi Saito and Fusao Tomita "Difructose Anhydrides: Their Mass-Production and Physiological Functions" Biosci. Biotechnol. Biochem. 2000, 64(7), 1321-1327.) and Armarego (U', of record.)

A method of purifying a DFA III solution comprising contacting the solution with activated carbon, phase separating the solution, and recovering purified DFA III is claimed. The claims are also in general further drawn to percentages, relative quantities, and dimensions of the components.

Tanaka (AP,N') teaches the DFA product in solution (500 ml extract); less than 70% pure (0.5g DFA recoverable per 500 ml extract); the use of yeast, including fermenting with the aerobe *A. ureafaciens*; defecation (filtering boiled/sliced burdock); adsorption onto active carbon; filtering to separate the solid carbon adsorbate from the liquid filtrate; and chromatographing with HIGH-FLOW SUPERCELL (eluted with 5% ethanol) in the purification

of the difructose dianhydride product (English abstract; English translation: page 4, ¶1-2; page 5 ¶1 and 3).

Uchiyama (A) teaches a process for preparing DFA III comprising obtaining DFA via a centrifuged *Arthrobacter ilicus* cell-filtrate; adjusting the filtrate concentration (from 150mL to 10mL) under reduced pressure; passing the filtrate through and further purifying the DFA III-containing fraction by an activated carbon/CELITE column, and finally concentrating to dryness the eluted peaks to yield purified DFA III. Uchiyama also teaches that the inulin-lytic enzyme may be provided as the enzyme *per se* (an extract) or in the form of the obligate aerobe microorganism producing the enzyme (e.g. column 5, lines 4-7) and that inulin may be obtained from a variety of sources.

Tomita (N) teaches a method for purifying DFA III (Derwent- English abstract). Tomita teaches purification using centrifugation to defecate the suspended particles, and filtering by passage through activated carbon and silicates (i.e. CELITE) (Derwent- English abstract, lines 7-9). Tomita also teaches a purity of DFA III of less than 70% in that Tomita teaches a composition comprising 95% components other than inulin. Thus even 100% conversion of inulin to DFA III by the inulinase would produce a composition comprising no more than 5% DFA III. Tomita also teaches action of a fructosyltransferase upon a fructose/fructose-containing polymer by teaching the reaction of inulinase upon inulin to produce DFA III (Derwent- English abstract, line 1).

Saito (V") teaches mass production of DFA III from a variety of DFA III-producing organisms (table 1). Saito also teaches the benefit of purifying inulin from chicory (§1) and purifying DFA III with microorganisms producing inulase II (EC 2.4.1.93) including *Arthrobacter* sp H65-7, wherein DFA III is produced in a yield (purity) of 93% (page 1323, ¶(1); table 2). The purified composition is further purified, including by depleting the composition of fructose and liner oligosaccharides by yeast treatment (1323, §(1), ¶3).

Armarego (U') teaches that "purity is a matter of degree" and that absolute purity is an unattainable ideal (page 1, ¶1). Armarego teaches that carbon (charcoal/decolorizing carbon) is useful in the removal extraneous/contaminant material for solutions by the addition of a small amount of carbon to a solution, then filtered, and that a "greater degree of purity is also to be expected if the [crystallization] process is repeated several times" (page 12, "Recrystallization: Techniques", ¶2). Armarego further teaches that purification by filtration may be supplemented with filter aids, including the diatomaceous earth/silicates "CELITE, FLORISIL, or HYFLO-SUPERCEL" or substituted with various porosity filters (filter paper, glass fibre, sintered glass, NYLON, TEFLON, polyvinyl chloride filters, etc.) or centrifuged depending on the solvent and the nature of compounds in solution/suspension (e.g. particle size, (in)solubility)(page 13). Still further, Armarego teaches that purification of complex organic mixtures includes adsorption chromatography, wherein the adsorbents include "charcoal (usually mixed with kieselgurh or other form of diatomaceous earth, for example, the filter aid CELITE)" (e.g. "Graded Adsorbents and Solvents", page 18).

Tanaka differs from the instant claims in that Tanaka appears to be silent with respect to the percentage purity and brix of the starting material and product; the quantity and quality (particle size/surface area/mesh) of carbon adsorbent used; and the sequence of contacting of the solid, liquid, and carbon.

Uchiyama differs from the instant claim in that Uchiyama appears to be silent with respect to the claimed percentages, amounts, and dimensions of the carbon and DFA compositions.

Tomita differs from the instant claims in that Tomita appears to be silent with respect to the claimed purity of DFA, percentage of carbon.

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to have used any active carbon source or any DFA III and to purify the composition to the desired purity (e.g. 70%(w/w)) in the methods of Tanaka/Uchiyama/Tomita, because Saito teaches that DFA III isolated from a variety of sources was known at the time of the invention and because Armarego teaches that purity is merely a matter of degree whereby a variety of techniques are well-established and routinely optimized for the purpose of purification, including filtration/adsorption with silicates (e.g. diatomaceous/Fuller's earth), silica, activated carbon, etc.

One would have been motivated to purify the compositions with active carbon, because Tanaka/Uchiyama teach in general that DFA may be purified using active carbon and HIGH-FLOW SUPERCELL/CELITE. The quality (purity, brix) of the DFA of Tanaka appears to be an obvious variant of that instantly claimed in that the compositions appear to have the same

chemical core, obtained from the same composition (and/or commercially available materials), and would thus be expected to have similar chromatographic selectivity properties, especially as said purification relates not to the DFA but to the adsorption of the impurities therewith.

Additionally, the carbon of the prior art is deemed to be an obvious variant of the instantly claimed activated carbon in that both materials comprise active carbon and are useful for the same purpose intrinsic to activated carbon (purification, decolorizing, deodorizing, etc.).

Armarego is relied upon for the reasons discussed above for the general benefit of purification, including adsorption with activated carbon. If not expressly taught by Armarego, based upon the overall beneficial teaching provided by this reference with respect to purification including purification with activated carbon in the manner disclosed therein, the adjustments of particular conventional working conditions (e.g., determining one or more suitable particle size ranges in which to perform such a purification/adsorption), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan, the skilled artisan seeking to adsorb a compound with carbon would recognize that increasing surface area (e.g. granular/powder/15-200 micron granules) would increase contact/absorption of molecules upon the carbon/activated carbon particles.

Thus the contacting of each of the starting material DFA and the carbon of any size, purity, or quantity would still be expected to interact in the manner claimed (increasing the purity of the composition), especially in the absence of criticality or objective evidence to the contrary.

One would have had a reasonable expectation of success in making a purified DFA III composition, because the success depends upon contacting a DFA composition of known core structure, with activated carbon of known activity, in a known method (contacting/adsorbing), to

yield a predictable result (increased purity/ removal of adsorbed impurities) and well within the purview of the skilled artisan.

Tanaka and Saito are relied upon for the reasons discussed above. If not expressly taught by Tanaka/Saito, based upon the overall beneficial teaching provided by the references with respect culturing an aerobic bacteria, extent of purification of reagents/products, and proportions of ingredients in the manner disclosed therein, the adjustments of particular conventional working conditions (e.g., determining one or more suitable concentration ranges (e.g. aerobe culturing oxygenation/aeration; quantities, qualities, and proportions of composition components in which to perform such a purification), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Furthermore, selection of any order of mixing ingredient is *prima facie* obvious in the absence of new or unexpected results (see, e.g., *In re Gibson*, 5 USPQ 230 - CCPA 1930). MPEP § 2144.04. Also, Selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results (see, e.g., *Ex parte Rubin*, 128 USPQ 440, 1959, and *In re Burhans*, 154 F.2d 690, 69 USPQ 330 - CCPA 1946) MPEP § 2144.04.

Please note, claims 50-52 have been included in this rejection since the treating of inulin does not require an isolated, purified, or other manipulation which would distinguish an inulin conversion by an organism containing the enzyme from inulin conversion by an (inulin) fructosyltransferase enzyme *per se*.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the

forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments filed August 12, 2009, are acknowledged. Applicant has that the prior art of record does not teach powdered activated carbon having the claimed particle size and has also argued that the instant invention provides superior results.

In regards to Applicant's argument that the prior art does not teach activated carbon of 15-200 micron particle size/powder this is not persuasive because, for the reasons above, the selection of activated carbon particle size is a mere matter of judicious choice for the person of ordinary skill in the art.

In regards to Applicant's arguments that the prior art does not teach the superior results of the instant invention, this is not found to be persuasive, because the evidence provided (e.g. table, Remarks, page 10) has not been provided in an affidavit or declaration under 37 CFR 1.132 and the arguments of counsel cannot take the place of evidence in the record. *In re*

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Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the Applicant (MPEP 716.01(b)). In this case, the arguments and the data there in the 8/12/09 reply are not supported by any affidavit or declaration and thus the alleged unexpectedness or superiority (versus the expectation of increased surface area upon adsorption/decolorizing/deodorizing); the statistical and practical significance (probative value) of the results; and the nexus of the presented results to the superior/unexpected results are not persuasive over the arguments of record.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. KOSAR whose telephone number is (571)270-3054. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday,EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron J Kosar/
Examiner, Art Unit 1651

/Christopher R. Tate/
Primary Examiner, Art Unit 1655